Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

Required Advisory Statements for Medicine Labels

Update 6

February 2011

This page has been left intentionally blank.

TABLE OF CONTENTS

This page has been left intentionally blank.

REQUIRED ADVISORY STATEMENTS FOR MEDICINE LABELS – PROPOSED UPDATE 6

PURPOSE

This document is to advise stakeholders of the proposed changes to the *Required Advisory Statements for Medicine Labels* (RASML) *(Edition 1, incorporating updates 4 and 5)* dated February 2011.

REQUEST TO STAKEHOLDERS

Stakeholders are requested to review and comment on the proposed changes. Responses should include:

- Whether or not you support the proposed changes. If you do not support a change, you may make suggestions for an alternative acceptable to you.
- An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

Responses should be sent to the Therapeutic Goods Administration (TGA) **no later than six (6) weeks from the date this consultation paper is posted on the TGA website. The deadline for submissions is by close of business Friday, 1 April 2011.**

Please head all responses: "RASML Update 6 – Response to Consultation"

Responses may be sent by mail, fax or e-mail as shown below.

Mail: RASML Document Manager
OTC Medicines Evaluation
Office of Medicines Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Fax: [redacted]

E-mail: otc.medicines@tga.gov.au

If you wish to discuss the proposed amendments, please call 1800 020 653.
The TGA has specifically invited comment on the proposed amendments from the following organisations. You may wish to consider submitting your response to one of these organisations, for incorporation in its overall response, rather than submission direct to the TGA:

- ACCORD Australasia Limited
- Australian Self-Medication Industry Inc. (ASMI)
- Complementary Healthcare Council of Australia (CHC)

- Consumers' Health Forum (CHF)
- Generic Medicines industry Association (GMiA) of Australia
- Medicines Australia (MA)
- Pharmaceutical Society of Australia (PSA)
- Pharmacy Guild of Australia

BACKGROUND INFORMATION TO RASML UPDATES

The *Therapeutic Goods Order No. 69* (TGO 69) – *General requirements for labels for medicines* (the Labelling Order) makes it mandatory for medicine labels to include any label advisory statements specified in the RASML. The RASML was established in July 2004 to physically separate all mandatory label advisory statements for Over-The-Counter (OTC) and complementary medicines from the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) and the *Therapeutic Goods Regulations 1990* (the 'Regulations') to a new separate document which could be updated at regular intervals without issuing an entirely new Labelling Order each time.

Since 2004 the RASML has been updated four times and therefore the current RASML at the TGA website is Update 4.

Update 5 was drafted in 2009 and was released for the public consultation process in July 2009. As a result of the public consultation period, the RASML Update 5 was amended and agreed upon by the Therapeutic Goods Committee in November 2009. However, it was never published due to upcoming amendments in the *Therapeutic Goods Act 1989* and the version of RASML in use is the RASML Update 4.

From 30 March 2010, a new clearer legal basis for the RASML was commenced and the RASML will become a legislative instrument. This change was made by the *Therapeutic Goods Amendment (2009 Measures No 2) Act 2009* which amended the *Therapeutic Goods Act 1989*.

Once RASML becomes a legislative instrument, the TGA will set out an effective process for updating RASML regularly. This process will ensure that the RASML provides the latest updated information on OTC and complementary medicine labels' advisory statements for stakeholders.

This update, now released for public consultation, will bring together the Update 5, the outcomes of the *Australian Regulatory Guidelines for OTC Medicines* (ARGOM) review process and the recent additions/amendments in relation to the complementary medicines in one document.

To ensure consistency in our public consultation processes, the proposed changes to the RASML are being consulted on as RASML Update 6. Once the changes to the RASML are finalised, and the legal process for it to become a legislative instrument has been completed, the final version will be published as the RASML version 1.

SECTION 1 – MEDICINES TO WHICH ADVISORY STATEMENTS APPLY

1. Summary of Proposed Changes

Substance	Change type
Activated charcoal	Amendment
Ademetionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	Amendment
(S)-S-Adenosylmethionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	Amendment
Alpha hydroxy acids	New entry
Amethocaine	New entry
Antihistamines *(Entry 1 of 2)*	Amendment
Antihistamines *(Entry 2 of 2)*	New entry
Arginine	Amendment
Aspartame	New entry
Aspirin	Amendment
Azadirachta indica (Neem) *(Entry 1 of 2)*	Amendment
Backhousia citriodora	Amendment
Benzocaine	New entry
Benzydamine	New entry
Bovine colostrum powder	Amendment
Bovine lactoferrin	Amendment
Bovine whey IG-rich fraction	New entry
Butoconazole	Amendment
Butyl ester of pvm/ma copolymer	New entry
Calcium sodium caseinate	Amendment
Camphor	Amendment
Canarium indicum L. var indicum	Amendment
Carthamus tinctorius flower	New entry
Charcoal – activated	Amendment
Chelidonium majus	Amendment

Substance	Change type
Chlorhexidine	Amendment
Choline salicylate	New entry
Cinchocaine	New entry
Citric acid and other fruit acids	New entry
Clotrimazole	Amendment
Coal tar	New entry
Colostrum powder – bovine	Amendment
Creatine	Amendment
Creatine monohydrate	Amendment
Creatine phosphate	Amendment
DEA-Oleth-3 phosphate	New entry
Diclofenac *(Entry 1 of 3)*	New entry
Diclofenac *(Entry 2 of 3)*	Amendment
Diclofenac *(Entry 3 of 3)*	Amendment
Diethylhexyl-2,6-naphthalate	New entry
Diphenhydramine	New entry
Doxylamine	New entry
Econazole	Amendment
Erythrulose	New entry
Ethohexadiol	New entry
Ethyl butylacetyl-aminopropionate	New entry
Fluorides	Amendment
Flurbiprofen	Amendment
Glycollic acid	New entry
High selenium yeast	Amendment
Honey	Amendment
Hydrolysed milk protein – alpha casozepine enriched	Amendment
Hydroquinone	Amendment
Hydroxyanthracene derivatives	Amendment
Hypericum perforatum	Amendment
Ibuprofen *(Entry 1 of 4)*	New entry

Substance	Change type
Ibuprofen *(Entry 2 of 4)*	Amendment
Ibuprofen *(Entry 3 of 4)*	Amendment
Ibuprofen *(Entry 4 of 4)*	Amendment
Imidazoles	New entry
Indomethacin	New entry
Ketoprofen *(Entry 1 of 3)*	New entry
Ketoprofen *(Entry 2 of 3)*	Amendment
Ketoprofen *(Entry 3 of 3)*	Amendment
Kunzea ambigua	Amendment
Lactic acid	New entry
Lactoferrin – bovine	Amendment
Lansoprazole	New entry
Lignocaine	New entry
Lindane	New entry
Mefenamic acid	Amendment
Miconazole	Amendment
Naphazoline *(Entry 1 of 2)*	Amendment
Naphazoline *(Entry 2 of 2)*	New entry
Naproxen	Amendment
Nasal decongestant preparations	New entry
Octylbicycloheptene dicarboximide	New entry
Omega-3 fish oil phytosterol esters	New entry
Omeprazole	New entry
Oxiconazole	New entry
Oxymetazoline	Amendment
Pantoprazole	Amendment
Paullinia cupana	Amendment
Phenylephrine *(Entry 1 of 3)*	Amendment

Substance	Change type
Phenylephrine *(Entry 2 of 3)*	New entry
Phenylephrine *(Entry 3 of 3)*	New entry
Piperonyl butoxide	New entry
Pollen	New entry
Potassium chloride	New entry
Povidone-iodine/iodine	New entry
Pseudoephedrine	New entry
Psyllium	Amendment
Pyrethrins	New entry
Pyridoxal	Amendment
Pyridoxamine	Amendment
Pyridoxine	Amendment
Rabeprazole	New entry
Royal jelly	Amendment
Selenium yeast – high	Amendment
Selenocysteine	Amendment
Selenomethionine	Amendment
Senna *Aloe Cascara*	New entry
Sodium bicarbonate	New entry
Sodium fluoride	Amendment
Sodium selenate	Amendment
Sodium selenite	Amendment
Sodium sulfate	Amendment
(S)-S-Adenosylmethionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	Amendment
Stearamidopropyl PG-dimonium chloride phosphate	New entry
Stearyl dimethicone	New entry
Sucrose polycottonseedate	New entry
Sugar cane wax alcohols	Amendment
Tetrahydrozoline *(Entry 1 of 2)*	Amendment

Substance	Change type
Tetrahydrozoline *(Entry 2 of 2)*	New entry
Tioconazole	New entry
Tramazoline	Amendment
Ubidecarenone	Amendment
Vasoconstrictor eye drops	New entry
Vegetable oil phytosterol esters	Amendment
Vitamin B6	New entry
Vitamins	Amendment
Wheat dextrin	New entry
Xylometazoline	Amendment
Yeast – high selenium	Amendment

Details of the proposed changes are shown in the tables below. These tables show:

- the existing entry which requires amendment or inclusion of an additional information (showing proposed amendment in red and underlined and the deletions, if any, in the balloons in the margin);
- the proposed new entry (inserted details in red and underlined);
- an explanation for why the change is being proposed (in the 'comment' box); and
- proposed transitional arrangements (see Note 1 below).

NOTE 1: Unless otherwise advised, the normal RASML transition period would apply, that is, the new requirement would apply to all new products from the date the updated RASML is published, and to existing products one year from that date.

NOTE 2: A glossary for definitions can be found in the current RASML.

2. Amendments to the existing entries

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Activated charcoal	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	135, 136, 137
Ademetionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	43
(S)-S-Adenosylmethionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	43
Arginine	When included in Listed medicines~~Schedule 4 Part 1 of the Regulations~~.	155
Azadirachta indica (neem) *(Entry 1 of 2)*	When: (a) included in Listed medicines~~Schedule 4 Part 4 Division 2 of the Regulations~~; or (b) for the purpose of exclusion from the Schedules to the SUSMP when: (i) in preparations for human dermal therapeutic use; and (ii) in a container fitted with a child resistant closure.	120, 1, 14
Backhousia citriodora	When included in Listed medicines~~Schedule 4 Part 4 Division 2 of the Regulations~~.	90, 4, 15
Bovine colostrum powder	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	138, 139
Bovine lactoferrin	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	38
Calcium sodium caseinate	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	38
Canarium indicum L. var indicum	When included in Listed medicines~~in a listed medicine (refer Listing Notice 2005 (No 1))~~.	156
Charcoal – activated	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	135, 136, 137

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Chelidonium majus	When the preparation is in Listed medicines for oral use, OTHER THAN homoeopathic preparations containing *Chelidonium majus* in concentrations more dilute than a 1000-fold dilution of the mother tincture.	157, 152
Colostrum powder – bovine	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	138, 139
Creatine	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	67
Creatine monohydrate	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	67
Creatine phosphate	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	67
High selenium yeast	When included in Listed medicines~~non-prescriptioSchedule 4 Part 5 Division 3 of the Regulations~~.	27, 28
Honey	When included in Listed medicines~~non-prescriptioSchedule 4 Part 5 Division 3 of the Regulations~~.	7
Hydrolysed milk protein – alpha casozepine enriched	When included in Listed medicines~~non-prescription~~ for oral ingestion.	38, 139
Hydroxyanthracene derivatives *(Entry 1 of 3)*	When included in Listed medicines~~non-prescription~~ where the MRDD contains more than 10 mg and the product is promoted or marketed as a laxative.	4, 77, 184, 185, 186
Hydroxyanthracene derivatives *(Entry 2 of 3)*	When included in Listed medicines~~non-prescription~~ where the MRDD contains more than 10 mg and the product is NOT promoted or marketed as a laxative.	4, 77, 134, 184, 185, 186, 187
Hydroxyanthracene derivatives *(Entry 3 of 3)*	When included in Listed medicines~~non-prescription~~ where the MRDD contains 10 mg or less and the product is promoted or marketed as laxative.	4, 77, 184, 185
Hypericum perforatum	When included in Listed medicines~~non-prescriptionSchedule 4 Part 4 Division 2 of the Regulations~~.	44, 68
Kunzea ambigua	When included in Listed medicines~~non-prescriptionSchedule 4 Part 4 Division 2 of the Regulations~~.	119, 1, 116

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Lactoferrin – bovine	When included in Listed medicines~~non-prescriptionSchedule 4 Part 5 Division 3 of the Regulations~~.	38
Paullinia cupana	When included in Listed medicines~~non-prescriptionSchedule 4 Part 4 Division 2 of the Regulations~~.	36, 37
Psyllium	When included in Listed medicines~~non-prescription~~ for oral ingestion and the product contain dosage instructions for children.	190
Selenium yeast – high	When included in Listed medicines~~non-prescriptionSchedule 4 Part 5 Division 3 of the Regulations~~.	27, 28
Selenocysteine	When included in Listed medicines~~non-prescriptionSchedule 4 Part 5 Division 3 of the Regulations~~.	27, 28
Selenomethionine	When included in Listed medicines~~non-prescriptionSchedule 4 Part 5 Division 3 of the Regulations~~.	27, 28
Sodium selenate	When included in Listed medicines~~non-prescriptionSchedule 4 Part 5 Division 3 of the Regulations~~.	27, 28
Sodium selenite	When included in Listed medicines~~non-prescriptionSchedule 4 Part 5 Division 3 of the Regulations~~.	27, 28
Sodium sulfate	When included in Listed medicines~~non-prescriptionSchedule 4 Part 5 Division 3 of the Regulations~~.	134
(S)-S-Adenosylmethionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	When included in Listed medicines~~non-prescriptionSchedule 4 Part 5 Division 3 of the Regulations~~.	43
Sugar cane wax alcohols	When included in Listed medicines~~non-prescriptionSchedule 4 Part 5 Division 3 of the Regulations~~.	15
Ubidecarenone	When included in Listed medicines~~non-prescriptionSchedule 4 Part 5 Division 3 of the Regulations~~.	41
Vegetable oil phytosterol esters	When included in Listed medicines~~non-prescription~~ for oral ingestion.	15, 191

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Vitamins *(See also Pyridoxal, Pyridoxamine, Pyridoxine, Vitamin A)*	When included in Listed medicines.	34 or 35
Yeast – high selenium	When included in Listed medicines~~Schedule 4 Part 5 Division 3 of the Regulations~~.	27, 28
Comment:	These amendments simplify and ensure consistency in references to Listed medicines, which are outlined in Schedule 4 of the Regulations.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Chlorhexidine	When included in topical products for human use, including preparations for topical use on mucosal surfaces.	79, 85,114, 212
Comment:	Chlorhexidine was included in the consultation document for update 5, which was approved by the Therapeutic Goods Committee in 2009 but was not implemented as the current update of RASML. A new RASML statement 212: 'WARNING – This product contains chlorhexidine. Severe allergic reactions can occur. Stop use if this occurs' is proposed to be included on labelling of all non-prescription products for mucosal surfaces containing chlorhexidine.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Fluorides	For the purpose of exclusion from the Schedules to the SUSMP when: (a) in dental hygiene products (other than pastes, powders or gels for the cleaning of teeth); and (b) the preparation contains 220 mg/kg or 220 mg/L or less of fluoride ion; and (c) in packs containing not more than 120 mg total fluoride fitted with a child-resistant closure.	(122, 150)[j], 13, 40, 210

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Comment:	The following RASML statements: · 13: Do not use if pregnant; · 40: Use of this product is not necessary in areas supplied with fluoridated water; and · 210: Do not use except on the advice of a dentist are proposed to be included on labelling of all non-prescription products for fluoride containing products.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Flurbiprofen	When included in a Schedule to the SUSMP for topical use.	(126, 127, ~~18,~~ 149, 130, ~~133,~~ 159, 160, 176, 192, 200, 201)[j]
Comment:	The following RASML statements: · 18: Do not use during the last three months of pregnancy; and · 133: Unless a doctor has told you to, do not use [this product/*insert name of product*] if you are pregnant are proposed to be replaced by RASML statement 176: 'Do not use [this product/insert the name of the product] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy'. The following RASML statements: · 192: Ask your doctor or pharmacist before use if you are dehydrated, or have diarrhoea or vomiting; · 200: Do not use if you have impaired kidney function; and · 201: Do not use if you have heart failure are proposed to be included on labelling of all non-prescription products containing flurbiprofen to align with the other non-prescription NSAID products. The statement 149 is amended to incorporate all anti-inflammatory medicines (see also Section 2).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Hydroquinone	When included in Schedule 2 to the SUSMP.	(113, 9, 83, 114, 115)[j], 211
Comment:	The RASML statement 211: 'Long term and repeated use should be avoided because darkening of the skin could occur' is proposed to be included on labelling of all non-prescription products containing hydroquinone as required by current ARGOM.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Mefenamic acid	When: (a) included in a Schedule to the SUSMP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160, 192, 200, 201)[j]
Comment:	The RASML statements: · 192: Ask your doctor or pharmacist before use if you are dehydrated, or have diarrhoea or vomiting; · 200: Do not use if you have impaired kidney function; and · 201: Do not use if you have heart failure are proposed to be included on labelling of all non-prescription products containing mefenamic acid to align with the other non-prescription NSAID products. The statement 149 is amended to incorporate all anti-inflammatory medicines (see also Section 2).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Naproxen *(Entry 1 of 2)*	When: (a) included in a Schedule to the SUSMP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160, 192, 200, 201)[j]
Naproxen *(Entry 2 of 2)*	When: (a) included in a Schedule to the SUSMP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160, 176, 192, 200, 201)[j]
Comment:	The RASML statements: · 192: Ask your doctor or pharmacist before use if you are dehydrated, or have diarrhoea or vomiting; · 200: Do not use if you have impaired kidney function; and · 201: Do not use if you have heart failure are proposed to be included on labelling of all non-prescription products containing naproxen to align with the other non-prescription NSAID products. The statement 149 is amended to incorporate all anti-inflammatory medicines (see also Section 2).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Royal jelly	When included in a Listed medicine.	8, 170[k,l],171
Comment:	RASML statement 8: 'Not suitable for use by children under 15' is proposed to be included on labelling of all listed medicine products containing royal jelly. The requirement for the label statement is an existing ELF rule.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Zingiber officinale	When included in a Listed medicine; (a) when the extraction ratio is 25:1 or higher; and (b) when the equivalent dry weight per dosage unit is 2 g or higher.	162, 163
Comment:	Amendment in the format is proposed for the consistency of the RASML document.	

3. Amendments to the existing multiple entries

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Aspirin *(Entry 1 of 7)*	For the purpose of exclusion from the Schedules to the SUSMP, when: (a) each dosage unit contains more than 100 mg of aspirin; and (b) the preparation is NOT indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation.	10, 126, 127, 128, 130, 140, 141, 142, 159, 176
Aspirin *(Entry 2 of 7)*	For the purpose of exclusion from the Schedules to the SUSMP, when: (a) each dosage unit contains more than 100 mg of aspirin; and (b) the preparation is indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation.	10, 126, 127, 128, 130, 140, 141, 159, 176
Aspirin *(Entry 3 of 7)*	For the purpose of exclusion from the Schedules to the SUSMP, when: (a) each dosage unit contains 100 mg or less of aspirin; and (b) the preparation is indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation.	10, 63, 126, 127, 128, 130, 140, 141, 142, 159, 176
Aspirin *(Entry 4 of 7)*	When included in a Schedule to the SUSMP and: (a) the preparation is indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; or (b) in sustained release preparations containing 650 mg or more of aspirin.	10, 63[j], 126, 127, 128, 130, 140, 141, 142, 159, 176
Aspirin *(Entry 5 of 7)*	When included in a Schedule to the SUSMP, and: (a) the preparation is indicated exclusively for treatment of dysmenorrhoea; and (b) NOT in sustained release preparations containing 650 mg or more of aspirin; and (c) NOT in combination with other therapeutically active substances (other than an effervescent agents).	10, 126, 127, 128, 130, 140, 141, 142, 159

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Aspirin *(Entry 6 of 7)*	When included in a Schedule to the SUSMP, and: (a) in combination with other therapeutically active substances (other than ~~an~~ effervescent agents); and (b) NOT in sustained release preparations containing 650 mg or more of aspirin; and (c) the preparation is NOT indicated: (i) for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; or (ii) exclusively for treatment of dysmenorrhoea.	10, 126, 127, 128, 130, 140, 141, 159, 176
Aspirin *(Entry 7 of 7)*	When included in a Schedule to the SUSMP, and: (a) NOT in combination with other therapeutically active substances (other than ~~an~~ effervescent agents); and (b) NOT in sustained release preparations containing 650 mg or more of aspirin; and (c) the preparation is NOT indicated: (i) for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; or (ii) exclusively for treatment of dysmenorrhoea.	10, 126, 127, 128, 130, 140, 141, 142, 159, 176

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Comment:	The amendment '.. the prevention of cardiovascular disease or for the..' is proposed to the conditions of aspirin entries 1, 2, 4, 6, and 7 as required by ARGOM and the SUSMP. The RASML statement 159: 'If you get an allergic reaction stop taking and see your doctor immediately' is proposed to be included on labelling of all non-prescription products containing aspirin to align with the other non-prescription NSAID products. In addition the following RASML statements are proposed to be included on labelling of all aspirin containing products that apply with the conditions in the entries of 3/7 and 4/7: · 126: Do not use [this product/*insert name of product*] if you have a stomach ulcer; · 127: Do not use [this product/*insert name of product*] if you are allergic to [*insert name substance*] or other anti-inflammatory medicines; · 128: Unless a doctor has told you to, do not use [this product/*insert name of product*] for more than a few days at a time; · 130: Unless a doctor has told you to, do not use [this product/*insert name of product*] if you have asthma; · 140: Unless a doctor has told you to, do not use [this product/*insert name of product*] with other medicines containing other anti-inflammatory medicines or other medicines that you are taking regularly; · 141: Unless a doctor has told you to, do not use [this product/*insert name of product*] in children under 12 years of age; · 142: See a doctor before taking [this product/*insert name of product*] for thinning the blood or for your heart; and · 176: Do not use [this product/*insert the name of the product*] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. The statements 140 and 159 are amended to incorporate all anti-inflammatory medicines (see also Section 2).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Camphor *(Entry 1 of 3)*	For the purpose of exclusion from the Schedules to the SUSMP when: (a) included as a natural component in essential oils containing greater than 2.5 per cent of camphor but 10 per cent or less of camphor; and (b) packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert.	1[a], 120[a], 222
Camphor *(Entry 2 of 3)*	For the purpose of exclusion from the Schedules to the SUSMP when: (a) in essential oils when the camphor is present as a natural component of the oil; and (b) packed in containers having: (i) a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or (ii) a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a], 222
Camphor *(Entry 3 of 3)*	When: (a) included in a Schedule to the SUSMP; and (b) NOT in block, ball, disc or pellet form, enclosed in a device which, in normal use, prevents removal or ingestion of its contents.	11[j], 79[h], (123 or 124)[f], 222
Comment:	The RASML statement 222: 'Do not apply to infants under 12 months of age except on the advice of a doctor' is proposed to be included on labelling of all non-prescription products containing camphor as required by ARGOM.	

Medicines Containing …	**Which Meet The Following Conditions ...**	**Required Statement(s)**
Diclofenac *(Entry 1 of 3)*	For the purpose of exclusion from the Schedules to the SUSMP, when the preparation is for dermal use.	(127, 159)[j], 202
Diclofenac *(Entry 2 of 3)*	When: (a) included in a Schedule to the SUSMP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 130, 149, 159, 160, 192, 200, 201)[j]
Diclofenac *(Entry 3 of 3)*	When: (a) included in a Schedule to the SUSMP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 130, 149, 159, 160, 176, 192, 200, 201)[j]
Comment:	A new entry is included to incorporate all non-prescription products containing diclofenac for dermal use with the following RASML statements on the labelling: · 127: Do not use [this product/*insert name of product*] if you are allergic to [*insert name substance*] or other anti-inflammatory medicines; · 159: If you get an allergic reaction stop taking and see your doctor immediately; and · 202: Unless a doctor has told you to, do not use [this product / product name] with other medicines that you are taking regularly. The following RASML statements: · 192: Ask your doctor or pharmacist before use if you are dehydrated, or have diarrhoea or vomiting; · 200: Do not use if you have impaired kidney function; and · 201: Do not use if you have heart failure are proposed to be included on labelling of all non-prescription products containing diclofenac for oral use to align with the other non-prescription NSAID products. The statement 149 and 159 are amended to incorporate all anti-inflammatory medicines (see also Section 2).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Ibuprofen *(Entry 1 of 4)*	For the purpose of exclusion from the Schedules to the SUSMP in preparation for dermal use.	(127, 159)[j], 202
Ibuprofen *(Entry 2 of 4)*	When the preparation is indicated exclusively for the treatment of dysmenorrhoea. ~~For the purpose of exclusion from the Schedules to the SUSMP, when the preparation is for oral use and is indicated exclusively for the treatment of dysmenorrhoea.~~	126, 127, ~~151~~ 130, 149, ~~131, 132,~~ 159, 160, 192, 200, 201
Ibuprofen *(Entry 3 of 4)*	For the purpose of exclusion from the Schedules to the SUSMP, when: (a) the preparation is for oral use; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	126, 127, ~~151~~ 130, 131, 132, 149, 159, 160, 176, 192, 200, 201
Ibuprofen *(Entry 4 of 4)*	When: (a) included in a Schedule to the SUSMP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 130, 149, 159, 160, 176, 192, 200, 201)[j]

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Comment:	A new entry is included to incorporate all non-prescription products containing ibuprofen for dermal use with the following RASML statements on the labelling: · 127: Do not use [this product/*insert name of product*] if you are allergic to [*insert name substance*] or other anti-inflammatory medicines; · 159: If you get an allergic reaction stop taking and see your doctor immediately; and · 202: Unless a doctor has told you to, do not use [this product / product name] with other medicines that you are taking regularly. The following RASML statements: · 192: Ask your doctor or pharmacist before use if you are dehydrated, or have diarrhoea or vomiting; · 200: Do not use if you have impaired kidney function; and · 201: Do not use if you have heart failure are proposed to be included on labelling of all non-prescription products containing ibuprofen for oral use to align with the other non-prescription NSAID products. In addition RASML statement 149: 'Unless a doctor has told you to, do not use [this product/insert name of product] with other medicines containing [insert name of substance], aspirin or other anti-inflammatory medicines or other medicines that you are taking regularly' is proposed to be included on labelling of all ibuprofen containing products that apply with the conditions in the entries of 2 of 4 and 3 of 4. The statement 149 and 159 are amended to incorporate all anti-inflammatory medicines (see also Section 2).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Ketoprofen *(Entry 1 of 3)*	For the purpose of exclusion from the Schedules to the SUSMP, when the preparation is for dermal use.	(127, 159)[j], 202
Ketoprofen *(Entry 2 of 3)*	When: (a) included in a Schedule to the SUSMP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160, 192, 200, 201)[j]
Ketoprofen *(Entry 3 of 3)*	When: (a) included in a Schedule to the SUSMP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160, 176, 192, 200, 201)[j]
Comment:	A new entry is included to incorporate all non-prescription products containing ketoprofen for dermal use with the following RASML statements on the labelling: · 127: Do not use [this product/*insert name of product*] if you are allergic to [*insert name substance*] or other anti-inflammatory medicines; · 159: If you get an allergic reaction stop taking and see your doctor immediately; and · 202: Unless a doctor has told you to, do not use [this product / product name] with other medicines that you are taking regularly. The following RASML statements: · 192: Ask your doctor or pharmacist before use if you are dehydrated, or have diarrhoea or vomiting; · 200: Do not use if you have impaired kidney function; and · 201: Do not use if you have heart failure are proposed to be included on labelling of all non-prescription products containing ketoprofen for oral use to align with the other non-prescription NSAID products. The statement 149 and 159 are amended to incorporate all anti-inflammatory medicines (see also Section 2).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Phenylephrine *(Entry 1 of 3)* *(See also nasal decongestant preparations)*	When in nasal preparations for topical use.	76 [j]
Phenylephrine *(Entry 2 of 3)*	When in oral preparations (a) for the purpose of exclusion from the Schedules to the SUSMP; or (b) included in Schedule 2 to the SUSMP.	208, 209
Phenylephrine *(Entry 3 of 3)* *(See also vasoconstrictor eye drops)*	When in topical eye preparations (a) for the purpose of exclusion from the Schedules to the SUSMP; or (b) included in Schedule 2 to the SUSMP.	209, 226, 227, 228, 229
Comment:	As required by ARGOM, a new entry is included to incorporate all non-prescription products containing phenylephrine for oral use. The following RASML statements are proposed to be included on the labelling of these products: · 208: See your doctor before taking this product if you have high blood pressure or heart problems or are taking antidepressant medication; and · 209: [This product/Product name] may cause sleeplessness if it is taken up to several hours before going to bed. The second new entry is included to incorporate all non-prescription products containing phenylephrine for topical eye preparations with the following RASML statements on the labelling: · 209: [This product/Product name] may cause sleeplessness if it is taken up to several hours before going to bed; · 226: Prolonged use may be harmful; · 227: Consult a doctor or pharmacist if using other eye products; · 228: Do not use if you have glaucoma or other serious eye conditions; and · 229: If symptoms persist, consult a doctor.	

4. The proposed group entries (with new entries and/or with amendments to existing entries)

The purpose of group entries in the RASML is to include the label statements for non-prescription medicines containing certain substance groups in a similar manner as set out in the *Australian Regulatory Guidelines for OTC Medicines (Product Specific Requirements).*

Individual entries below are presented together with the group entries for purposes of public consultation only. In the final RASML, they will be organised in the alphabetical order with the rest of the entries.

Medicines Containing …	**Which Meet The Following Conditions ...**	**Required Statement(s)**
Alpha hydroxy acids, including: · glycollic acid · lactic acid · citric acid and other fruit acids	When in preparations for topical use.	194, 195, 213, 214, 218
Citric acid and other fruit acids *(See also Alpha hydroxy acids)*	When in preparations for topical use.	194, 195, 213, 214, 218
Glycollic acid *(See Alpha hydroxy acids)*	When in preparations for topical use.	194, 195, 213, 214, 218
Lactic acid *(See Alpha hydroxy acids)*	When in preparations for topical use.	194, 195, 213, 214, 218
Comment:	A new group entry for ‘alpha hydroxy acids’ and three new individual entries, ‘citric acid and other fruit acids’, ‘glycollic acid’ and ‘lactic acid’ are included to incorporate alpha hydroxy acid containing products. The following RASML statements: · 194: This product may make your skin more sensitive to sunlight; · 195: Sun exposure should be limited by using a sunscreen and by wearing protective clothing; · 213: Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use; · 214: If you have sensitive skin, test this product on a small area of skin before applying it to a large area; and · 218: Not recommended for use on children and infants are proposed to be included on labelling of all non-prescription products containing any of the alpha hydroxyl acids; ‘glycollic acid’, ‘lactic acid’, ‘citric acid or other fruit acids’. In the final RASML document, the individual entries will be located in alphabetical order.	

Medicines Containing …	**Which Meet The Following Conditions ...**	**Required Statement(s)**
Antihistamines *(Entry 1 of 2)*	When: (a) included in a Schedule to the SUSMP; and (b) not separately specified in this Table and they are NOT any one or more of: (i) dermal, ocular, parenteral and paediatric preparations; or (ii) oral preparations of astemizole, desloratidine, fexofenadine, loratadine or terfenadine; or (iii) nasal preparations of azelastine; or (iv) preparations for short-term use in insomnia.	(46 and 49 and 47)[j] or (48 and 50)[j]
Antihistamines, including: *(Entry 2 of 2)* · Diphenhydramine · Doxylamine · Promethazine	When included in Schedule 3 to the SUSMP for the short-term use in insomnia.	15, 206, 220, 221
Diphenhydramine *(See also antihistamines)*	When included in Schedule 3 to the SUSMP for short-term use in insomnia.	15, 206, 220, 221
Doxylamine *(See also antihistamines)*	When included in Schedule 3 to the SUSMP for short-term use in insomnia.	15, 206, 220, 221
Promethazine *(See also antihistamines)*	When included in Schedule 3 to the SUSMP for short-term use in insomnia.	15, 206, 220, 221
Comment:	A new group entry for ‘antihistamines’ and three new individual entries, ‘diphenhydramine’,’doxylamine’ and ‘promethazine’ are included to incorporate antihistamine containing products for the short-term use in insomnia. The following RASML statements: · 15: Not recommended for use by pregnant or lactating women; · 206: This product is for temporary use; · 220: This product should be taken on medical or pharmacist advice; and · 221: This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol. are proposed to be included on labelling of all non-prescription products containing any of the antihistamines; diphenhydramine, doxylamine or promethazine. In the final RASML document, the individual entries will be located in alphabetical order.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Imidazoles, including; · Butoconazole · Clotrimazole · Econazole · Miconazole · Oxiconazole · Tioconazole	In vaginal preparations when included in Schedule 3 to the SUSMP.	(13, 66, 74, 75,)[j]
Butoconazole *(See also imidazoles)*	In vaginal preparations when included in Schedule 3 to the SUSMP.	(13, 16, 66, 74, 75)j
Clotrimazole *(See also imidazoles)*	In vaginal preparations when included in Schedule 3 to the SUSMP.	(13, 16, 66, 74, 75)j
Econazole *(See also imidazoles)*	In vaginal preparations when included in Schedule 3 to the SUSMP.	(13, 16, 66, 74, 75)j
Miconazole *(See also imidazoles)*	In vaginal preparations when included in Schedule 3 to the SUSMP.	(13, 16, 66, 74, 75)j
Oxiconazole *(See also imidazoles)*	In vaginal preparations when included in Schedule 3 to the SUSMP.	(13, 66, 74, 75)j
Tioconazole *(See also imidazoles)*	In vaginal preparations when included in Schedule 3 to the SUSMP.	(13, 66, 74, 75)j
Comment:	A new group entry for 'imidazoles' and two new individual entries, 'oxiconazole' and 'tioconazole' are included to incorporate imidazole containing products. The following RASML statements: · 13: Do not use if pregnant; · 66: Seek medical advice before first course of treatment; · 74: See a doctor if problem returns; and · 75: See a doctor (or) (dentist) if no better after (Insert number of days as per approved Product Information) days, are proposed to be included on labelling of all non-prescription products containing any of the imidazoles; butoconazole, clotrimazole, econazole, miconazole, oxiconazole or tioconazole as required by ARGOM. The RASML statement 13 is proposed to be included to the existing entries for butoconazole, clotrimazole, econazole and miconazole to align with the other entries in this group. In the final RASML document, the individual entries will be located in alphabetical order.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Nasal decongestant preparations, including: · Oxymetazoline · Phenylephrine · Tramazoline · Xylometazoline	When in nasal preparations for topical use and (a) for the purpose of exclusion from the Schedule to the SUSMP; or (b) included in Schedule 2 to the SUSMP.	76 [j]
Oxymetazoline *(See also nasal decongestant preparations)*	When in nasal preparations for topical use.	76 j
Phenylephrine *(Entry 1 of 3)* *(See also nasal decongestant preparations)*	When in nasal preparations for topical use.	76 [j]
Tramazoline *(See also nasal decongestant preparations)*	When in nasal preparations for topical use.	76 j
Xylometazoline *(See also nasal decongestant preparations)*	When in nasal preparations for topical use.	76 j
Comment:	A new group entry is included to incorporate nasal decongestant preparations with the RASML statement 76: 'If congestion persists for more than a few days, seek medical or pharmacist advice'. The statement is amended to incorporate all the nasal decongestant products (see also Section 2) and is proposed to be included on labelling of all non-prescription products containing any of the following; oxymetazoline, phenylephrine, tramazoline or xylometazoline. The existing RASML entries in this group are amended with the phrase '(See also nasal decongestant preparations)' to reflect back to the group entry. In the final RASML document, these individual entries will be located in alphabetical order. See also '3. Amendment for multiple entries' for phenylephrine in page 22.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Proton pump inhibitors including: · Lansoprazole · Omeprazole · Pantoprazole · Rabeprazole	When included in Schedule 3 to the SUSMP for oral preparations.	(60, 72)[j], 223
Lansoprazole *(See also proton pump inhibitors)*	When included in Schedule 3 to the SUSMP for oral preparations.	(60, 72)[j], 223
Omeprazole *(See also proton pump inhibitors)*	When included in Schedule 3 to the SUSMP for oral preparations.	(60, 72)j, 223
Pantoprazole *(See also proton pump inhibitors)*	When included in Schedule 3 to the SUSMP for oral preparations.	(60, 72)j, 223
Rabeprazole *(See also proton pump inhibitors)*	When included in Schedule 3 to the SUSMP for oral preparations.	(60, 72)j, 223
Comment:	A new group entry for 'proton pump inhibitors' and three new individual entries, 'lansoprazole', 'omeprazole' and 'rabeprazole' are included to incorporate proton pump inhibitor type of preparations. The following RASML statements: · 60: CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed; · 72: If symptoms persist or recur within two weeks of completing the course, consult a doctor; and · 223: Ask your doctor or pharmacist before use if you are taking other medicines regularly, are proposed to be included on labelling of all non-prescription products containing any of the proton pump inhibitors; lansoprazole, omeprazole, pantoprazole or rabeprazole. The existing RASML entry on pantoprazole is amended with the phrase '(See also proton pump inhibitors)' to reflect back to the group entry. In the final RASML document, the individual entries will be located in alphabetical order.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Vasoconstrictor eye drops including: · Naphazoline · Phenylephrine · Tetrahydrozoline	When in topical eye preparations.	226, 227, 228, 229
Naphazoline *(Entry 2 of 2)* *(See also vasoconstrictor eye drops)*	When in topical eye preparations.	226, 227, 228, 229
Phenylephrine *(Entry 3 of 3)* *(See also vasoconstrictor eye drops)*	When in topical eye preparations (c) for the purpose of exclusion from the Schedules to the SUSMP; or (d) included in Schedule 2 to the SUSMP.	209, 226, 227, 228, 229
Tetrahydrozoline *(Entry 2 of 2)* *(See also vasoconstrictor eye drops)*	When in topical eye preparations.	226, 227, 228, 229
Comment:	A new group entry is included to incorporate vasoconstrictor eye drop preparations. The following RASML statements: · 226: Prolonged use may be harmful; · 227: Consult a doctor or pharmacist if using other eye products; · 228: Do not use if you have glaucoma or other serious eye conditions; and · 229: If symptoms persist, consult a doctor, are proposed to be included on labelling of all non-prescription products containing any of the following; naphazoline, phenylepherine or tetrahydrozoline. The existing RASML entries in this group are amended with the phrase '(See also vasoconstrictor eye drops)' to reflect back to the group entry. In the final RASML document, these individual entries will be located in alphabetical order. See also '3. Amendment for multiple entries' for phenylephrine in page 22.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Vitamin B6 · pyridoxal · pyridoxamine · pyridoxine *(See also Vitamins)*	For the purpose of exclusion from the Schedules to the SUSMP when in preparations for human use containing 200 mg or less but more than 50 mg of [pyridoxal, pyridoxamine, pyridoxine] per recommended daily dose. (a) For single ingredient products; or (b) For multi-ingredient products.	178 or 179
Pyridoxal *(see also Vitamins and Vitamin B6)*	For the purpose of exclusion from the Schedules to the SUSMP when in preparations for human use containing 200 mg or less but more than 50 mg of pyridoxal per recommended daily dose.	178 or 179
Pyridoxamine *(see also Vitamins and Vitamin B6)*	For the purpose of exclusion from the Schedules to the SUSMP when in preparations for human use containing 200 mg or less but more than 50 mg of pyridoxamine per recommended daily dose.	178 or 179
Pyridoxine *(see also Vitamins and Vitamin B6)*	For the purpose of exclusion from the Schedules to the SUSMP when for human use in preparations for human use containing 200 mg or less but more than 50 mg of pyridoxine per recommended daily dose.	178 or 179
Comment:	A new group entry is included to incorporate Vitamin B6 containing products. The following RASML statements: · 178: WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible; or · 179: WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. Contains vitamin B6, are proposed to be included on labelling of all non-prescription medicines containing any of the following; pyridoxal, pyridoxamine or pyridoxine. The existing RASML entries in this group are amended with the phrase '(See also Vitamins and Vitamin B6)' to reflect back to the group entry. In the final RASML document, these individual entries will be located in alphabetical order.	

5. The proposed new single and/or multiple entries

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Aspartame	When for oral ingestion and included in Listed medicines.	193
Comment:	The new entry is proposed for aspartame with the RASML statement 193: 'Phenylketonurics are warned that this product contains aspartame (or words to that effect)' to be included on labelling of all listed medicines containing aspartame. The requirement for the label statement is an existing ELF rule.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Amethocaine	When: (a) included in Schedule 2 to the SUSMP; or (b) for the purpose of exclusion from the Schedules to the SUSMP when in preparations for dermal use containing 2 per cent or less of total local anaesthetic substances.	205, 217
Comment:	A new entry is included to incorporate all non-prescription products containing amethocaine for dermal use. The following RASML statements: · 205: Do not apply to large areas of the body, except on the advice of a healthcare practitioner; and · 217: If skin irritation occurs, discontinue use and seek medical advice, are proposed to be included on labelling of all non-prescription medicines containing amethocaine.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Benzocaine *(Entry 1 of 2)*	For the purpose of exclusion from the Schedules to the SUSMP when in preparations for dermal use containing 2 per cent or less of total local anaesthetic substances.	205, 217
Benzocaine *(Entry 2 of 2)*	For the purpose of exclusion from the Schedules to the SUSMP when in lozenges containing 30 mg or less of total local anaesthetic substances.	203, 204
Comment:	As required by ARGOM, a new entry is included to incorporate all non-prescription products containing benzocaine for dermal use with the following RASML statements on their labelling: · 205: Do not apply to large areas of the body, except on the advice of a healthcare practitioner; and · 217: If skin irritation occurs, discontinue use and seek medical advice, The second new entry is included to incorporate all non-prescription benzocaine containing products used as lozenges. The following RASML statements are proposed to be included on their labelling: · 203: Do not take hot food or drink soon after using this product because it may burn your mouth; and · 204: Do not give to children under 6 years of age, unless recommended by a doctor, pharmacist or dental professional.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Benzydamine	When: (a) For the purpose of exclusion from the Schedules to the SUSMP, when the preparation is for dermal use; or (b) when included in a Schedule to the SUSMP for topical use	(127, 159)[j]
Comment:	A new entry is included to incorporate all non-prescription products containing benzydamine for topical or dermal use. The following RASML statements: · 127: Do not use [this product/*insert name of product*] if you are allergic to [*insert name substance*] or other anti-inflammatory medicines; and · 159: If you get an allergic reaction stop taking and see your doctor immediately, are proposed to be included on labelling of all non-prescription benzydamine containing medicines.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Bovine whey IG-rich fraction	When for oral ingestion in Listed medicines.	139, 38
Comment:	The new entry is proposed for bovine whey IG-rich fraction to be included on labelling of all listed medicine products containing bovine whey IG-rich fraction with the following RASML statements: · 38: Derived from cows' milk; and · 139: This product is not suitable for use in children under the age of 12 months except on professional health advice. The requirement for the label statement is in the Listing Notice 2009 (No.5).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Butyl ester of pvm/ma copolymer	When used as an excipient in Listed medicines for topical use.	79, 215
DEA-Oleth-3 phosphate	When used as an excipient in Listed medicinesfor topical use.	79, 215
Diethylhexyl-2,6-naphthalate	When used as an excipient in Listed medicines for topical use.	215
Erythrulose	When used as an excipient in Listed medicines for topical use.	79
Ethyl butylacetyl-aminopropionate	When used as an excipient in Listed medicines for topical use.	215
Stearamidopropyl PG-dimonium chloride phosphate	When used as an excipient in Listed medicines for topical use.	215
Stearyl dimethicone	When used as an excipient in Listed medicines for topical use.	79, 215
Sucrose polycottonseedate	When used as an excipient in Listed medicines for topical use.	79, 215
Comment:	Several new entries are included to incorporate substances that required label statements when used as excipients in Listed medicines for topical use. The RASML statement 79: 'Avoid contact with eyes' is proposed to be included on labelling of all Listed medicines containing 'butyl ester of pvm/ma copolymer', 'DEA-Oleth-3 phosphate', 'erythrulose', 'Stearyl dimethicone' or 'Sucrose polycottonseedate'. The RASML statement 215: 'May be irritant to the eyes (or words to that effect)' is proposed to be included on labelling of all Listed medicines containing 'butyl ester of pvm/ma copolymer', 'DEA-Oleth-3 phosphate', 'Diethylhexyl-2,6-naphthalate', 'Ethyl butylacetyl-aminopropionate', 'Stearamidopropyl PG-dimonium chloride phosphate', 'Stearyl dimethicone' or 'Sucrose polycottonseedate'.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Carthamus tinctorius flower	When included in Listed medicines.	14
Comment:	The new entry is included for *Carthamus tinctorius* flower for oral use. The RASML statement 14: 'Do not use if pregnant or likely to become pregnant' is proposed to be included on labelling of all listed medicines containing *Carthamus tinctorius* flower.	
Transition:	This statement will apply to all existing Listed medicines from 1 July 2011.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Cinchocaine	For the purpose of exclusion from the Schedules to the SUSMP when in preparations for topical use other than eye drops containing 0.5 per cent or less of total local anaesthetic substances.	205, 217
Comment:	A new entry is included to incorporate all non-prescription products containing cinchocaine for topical use. The following RASML statements: · 205: Do not apply to large areas of the body, except on the advice of a healthcare practitioner; and · 217: If skin irritation occurs, discontinue use and seek medical advice, are proposed to be included on labelling of all non-prescription medicines containing cinchocaine.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Choline salicylate	When in preparations for topical oral use.	230
Comment:	A new entry is included to incorporate all non-prescription products containing choline salicylate for topical oral use. The following RASML statement: · 230: Do not exceed the recommended dose. Excessive or prolonged use can be harmful, is proposed to be included on labelling of all non-prescription medicines containing choline salicylate.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Coal tar	For topical use.	79, 90, 207
Comment:	As required by ARGOM, a new entry is included to incorporate all non-prescription products containing coal tar for topical use. The following RASML statements: · 79: Avoid contact with eyes; and · 90: If skin irritation occurs, discontinue use; and · 207: Do not use for prolonged periods except on the advice of a doctor, are proposed to be included on labelling of all non-prescription medicines containing coal tar.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Ethohexadiol	When used as an excipient in Listed medicines for topical use.	199
Comment:	A new entry is included for ethohexadiol when it is as an excipient in the products for topical use. The RASML statement 199: 'Contains [insert name of ingredient] (or words to that effect)' is proposed to be included on labelling of all listed medicines containing ethohexadiol.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Indomethacin	When included in Schedule 2 to the SUSMP for external use.	(127, 159)[j], 202
Comment:	A new entry is included to incorporate all non-prescription products containing indomethacin for external use with the following RASML statements on their labelling: · 127: Do not use [this product/*insert name of product*] if you are allergic to [*insert name substance*] or other anti-inflammatory medicines; · 159: If you get an allergic reaction stop taking and see your doctor immediately; and · 202: Unless a doctor has told you to, do not use [this product / *insert name of product*] with other medicines that you are taking regularly.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Lignocaine *(Entry 1 of 2)*	For the purpose of exclusion from the Schedules to the SUSMP when in preparations for dermal use containing 2 per cent or less of total local anaesthetic substances.	205, 217
Lignocaine *(Entry 2 of 2)*	For the purpose of exclusion from the Schedules to the SUSMP when in lozenges containing 30 mg or less of total local anaesthetic substances.	203, 204
Comment:	As required by ARGOM, a new entry is included to incorporate all non-prescription products containing lignocaine for dermal use with the following RASML statements on their labelling: · 205: Do not apply to large areas of the body, except on the advice of a healthcare practitioner; and · 217: If skin irritation occurs, discontinue use and seek medical advice. The second new entry is included to incorporate all non-prescription lignocaine containing products used as lozenges. The following RASML statements are proposed to be included on their labelling: · 203: Do not take hot food or drink soon after using this product because it may burn your mouth; and · 204: Do not give to children under 6 years of age, unless recommended by a doctor, pharmacist or dental professional.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Lindane	When included in Schedule 2 to the SUSMP for external use.	111, (224, 225)[j]
Comment:	As required by ARGOM, a new entry is included to incorporate all non-prescription products containing lindane for external use with the following RASML statements on their labelling: · 111: Do not use on broken skin; · 224: This preparation should be used with caution on infants, small children and pregnant of lactating women; and · 225: Medical advice should be sought before use.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Octylbicycloheptene dicarboximide	When used as an excipient in Listed medicines for topical use.	200
Piperonyl butoxide	When used as an excipient in Listed medicines for topical use.	200
Pyrethrins	When used as an excipient in Listed medicines for topical use.	200
Comment:	Several new entries are included to incorporate Listed medicines used as excipients in products for topical use. The RASML statement 200: 'Do not use if you have impaired kidney function' is proposed to be included on labelling of all listed medicines containing 'octylbicycloheptene dicarboximide', 'piperonyl butoxide' and 'pyrethrins'.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Omega-3 fish oil phytosterol esters	When in Listed medicines for oral ingestion.	15, 191
Comment:	A new entry is included for omega-3 fish oil phytosterol esters for oral use. The RASML statements: · 15: Not recommended for use by pregnant or lactating women; · 191: For lowering cholesterol uptake, there is no benefit of having more than 3 g/day of phytosterol from all sources, are proposed to be included on labelling of all Listed medicines containing omega-3 fish oil phytosterol esters. The requirement for the label statement is in the Listing Notice 2010 (No.1).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Pollen	When the ingredient is collected by bees and included in Listed medicines.	196
Comment:	A new entry is included for pollen for topical use. The RASML statement 196: 'This product contains pollen which can cause severe allergic reactions [or words to that effect].' is proposed to be included on labelling of all listed medicines containing pollen.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Potassium chloride *(Entry 2 of 3)*	When used in Listed medicines for oral rehydration therapy.	1, 165, 166, 197, 198
Potassium chloride *(Entry 3 of 3)*	When used in Listed medicines for oral rehydration therapy.	(1, 165, 166, 197, 198)[m]
Comment:	Two new entries are included to incorporate all Listed medicines containing potassium chloride for oral use. The RASML statements: · 1: Keep out of reach of children; · 165: Contains [amount of potassium] potassium; · 166: If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use; · 197: Use only as directed; and · 198: If diarrhoea persists, seek medical advice, are proposed to be included on labelling of all Listed medicines containing potassium chloride. Potassium chloride entry 3 of 3 contains an additional labelling requirement (m) for the treatment of children (see Section 3). The requirement for the label statement is in the Listing Notice 2009 (No.3).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Povidone-iodine/iodine *(See also iodine)*	For dermal use.	219
Comment:	As required by ARGOM, a new entry is included to incorporate all non-prescription products containing povidone-iodine/iodine for dermal use and the RASML statement 219: 'If skin irritation occurs, discontinue use immediately' is proposed to be included on labelling of all non-prescription products containing povidone-iodine/iodine.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Pseudoephedrine	When included in Schedule 3 to the SUSMP.	208, 209
Comment:	As required by ARGOM, a new entry is included to incorporate all non-prescription products containing pseudoephedrine for oral use with the following RASML statements on their labelling: · 208: See your doctor before taking this product if you have high blood pressure or heart problems or are taking antidepressant medication; and · 209: [This product/Product name] may cause sleeplessness if it is taken up to several hours before going to bed.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Senna *Aloe Cascara*	When in Listed medicines indicated for laxative use.	186
Comment:	A new entry is included for senna for oral use. The RASML statement 186: 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' is proposed to be included on labelling of all listed medicines containing senna.	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Sodium bicarbonate *(Entry 1 of 2)*	When included in Listed medicines for oral rehydration therapy.	197,198
Sodium bicarbonate *(Entry 2 of 2)*	When included in Listed medicines for oral rehydration therapy that are indicated for use in children.	(197, 198)[m]
Comment:	Two new entries are included to incorporate all Listed medicine products containing sodium bicarbonate for oral use. The RASML statements: · 197: Use only as directed; and · 198: If diarrhoea persists, seek medical advice, are proposed to be included on labelling of all Listed medicines containing sodium bicarbonate. Sodium bicarbonate entry 2 of 2 contains an additional labelling requirement (m) for the treatment of children (see Section 3). The requirement for the label statements are in the Listing Notice 2009 (No.3).	

Medicines Containing …	Which Meet The Following Conditions ...	Required Statement(s)
Wheat dextrin	When used as an excipient in Listed medicine for oral use.	199
Comment:	A new entry is included for wheat dextrin for oral use. The RASML statement 199: 'Contains [insert name of ingredient] (or words to that effect)' is proposed to be included on labelling of all listed medicines containing wheat dextrin.	

6. Archived Entries – Section 1 Medicines to Which Advisory Statements Apply

The following entries show requirements for labels of medicines that no longer apply. The date on which the entry ceased to be a requirement is shown in the "Date Ceased" column.

Medicines Containing …	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Astemizole	When included in a Schedule to the SUSDP	(42, 64)[j]	23 Jun 2004	[date to be inserted]
Ephedrine	In nasal preparations for topical use.	76[j]	23 Jun 2004	[date to be inserted]
Ibuprofen *(Entry 4 of 5)*	When: A) included in a Schedule to the SUSMP; and B) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160)[j]	23 Apr 2008	[date to be inserted]
Mefenamic acid *(Entry 3 of 3)*	When: a) included in a Schedule to the SUSMP; and **B)** the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160, 176, 192, 200, 201)[j]	10 Sep 2008	[date to be inserted]
Terfenadine	When included in a Schedule to the SUSDP.	(42, 64)[j]	23 Jun 2004	[date to be inserted]
Tranexamic acid	When included in Schedule 3 to the SUSDP.	66[j]	23 Jun 2004	[date to be inserted]

SECTION 2 - THE PROPOSED ADVISORY STATEMENTS

The following table gives details of the text to be included on the labels of medicines specified in Section 1.

1. Summary of Proposed Changes

It is proposed to:

- archive superseded statements 129 and 151;
- amended statements 76, 140 and 149 to include all the medicines in that group; and
- add statements 192 - 229

2. Superseded advisory statements

No	Statement Text	Gazettal Date	Date Ceased
129	Unless a doctor has told you to, do not use [this product/*insert name of product*] with other medicines containing aspirin or other anti-inflammatory medicines or other medicines that you are taking regularly.	23 Jun 2004	[date to be inserted]
151	Unless a doctor has told you to, do not use [this product/*insert name of product*] with other medicines containing ibuprofen, aspirin or other anti-inflammatory medicines or other medicines that you are taking regularly.	1 Jun 2005	[date to be inserted]

3. Amended advisory statements

No	Statement Text
76	If congestion persists for more than a few days, seek medical or pharmacist advice.~~If congestion persists, consult your doctor or pharmacist.~~
140	Unless a doctor has told you to, do not use [this product/insert name of product] with other medicines containing ~~aspirin or~~ other anti-inflammatory medicines or other medicines that you are taking regularly.
149	Unless a doctor has told you to, do not use [this product/*insert name of product*] with other medicines containing [insert name of substance], aspirin or other anti-inflammatory medicines or other medicines that you are taking regularly.~~Unless a doctor has told you to, do not use [this product/insert name of product] with other medicines containing [insert name of substance] or other anti-inflammatory medicines.~~

4. Added new advisory statements

No	Statement Text
192	Ask your doctor or pharmacist before use if you are dehydrated, or have diarrhoea or vomiting.
193	Phenylketonurics are warned that this product contains aspartame (or words to that effect).
194	This product may make your skin more sensitive to sunlight.
195	Sun exposure should be limited by using a sunscreen and by wearing protective clothing.
196	This product contains pollen which can cause severe allergic reactions [or words to that effect].
197	Use only as directed.
198	If diarrhoea persists, seek medical advice.
199	Contains [insert name of ingredient] (or words to that effect).
200	Do not use if you have impaired kidney function.
201	Do not use if you have heart failure.
202	Unless a doctor has told you to, do not use [this product / product name] with other medicines that you are taking regularly
203	Do not take hot food or drink soon after using this product because it may burn your mouth.
204	Do not give to children under 6 years of age, unless recommended by a doctor, pharmacist or dental professional.
205	Do not apply to large areas of the body, except on the advice of a healthcare practitioner.
206	This product is for temporary use.
207	Do not use for prolonged periods except on the advice of a doctor.
208	See your doctor before taking this product if you have high blood pressure or heart problems or are taking antidepressant medication.
209	[This product/Product name] may cause sleeplessness if it is taken up to several hours before going to bed.
210	Do not use except on the advice of a dentist.
211	Long term and repeated use should be avoided because darkening of the skin could occur.
212	WARNING – This product contains chlorhexidine. Severe allergic reactions can occur. Stop use if this occurs.
213	Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use.

No	Statement Text
214	If you have sensitive skin, test this product on a small area of skin before applying it to a large area
215	May be irritant to the eyes (or words to that effect)
216	Will irritate the eyes
217	If skin irritation occurs, discontinue use and seek medical advice.
218	Not recommended for use on children and infants.
219	If skin irritation occurs, discontinue use immediately.
220	This product should be taken on medical or pharmacist advice.
221	This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.
222	Do not apply to infants under 12 months of age except on the advice of a doctor.
223	Ask your doctor or pharmacist before use if you are taking other medicines regularly.
224	This preparation should be used with caution on infants, small children and pregnant of lactating women.
225	Medical advice should be shought before use.
226	Prolonged use may be harmful
227	Consult a doctor or pharmacist if using other eye products.
228	Do not use if you have glaucoma or other serious eye conditions.
229	If symptoms persist, consult a doctor.
230	Do not exceed the recommended dose. Excessive or prolonged use can be harmful.

SECTION 3 - ADDITIONAL REQUIREMENTS

The following table gives details of additional requirements prescribed for certain advisory statements, as specified in Section 1.

1. Summary of Proposed Changes

It is proposed to:

- amend requirement d); and
- add requirement m)

2. Amendments/changes to Additional Requirements

	Additional requirement	**Gazettal Date**
d	Statement(s) must be included on the label where the preparation is labelled to be used by females of child bearing age.~~for adult use.~~	23 Jun 2004
m	Statement(s) must be included on the label written with: **Age of child** — **Additional Directions** Under 6 months — Medical advice should be sought if diarrhoea persists for more than 6 hours. Under 3 years — Medical advice should be sought if diarrhoea persists for more than 12 hours. 3-6 years — Medical advice should be sought if diarrhoea persists for more than 24 hours. Over 6 years — Medical advice should be sought if diarrhoea persists for more than 48 hours.	[date to be inserted]